K120846

JUN - 8 2012

510(k) Summary

Puritan Liquid Amies Collection and Transport System

5.1 Sponsor

Puritan Medical Products LLC

31 School St., Guilford, ME 04443

Contact: Mehdi Karamchi

Telephone Number: 207-876-3311

Date: May 24, 2012

5.2 Device Name

Classification Name: Transport Culture Medium

Common Name: Microbiological Specimen Collection and Transport System

Proprietary Name: Puritan Liquid Amies Swab Collection and Transport System

5.3 Regulatory Information

A. Regulatory Section: 21 CFR 866.2900

B. Classification: Class I

C. Product Code: JTW, JTX

D. Panel: Microbiology

5.4 Predicate Device

BD (Copan) Liquid Amies Collection and Transport System

510K Number: K061301

5.5 Device Description

Puritan Liquid Amies Collection and Transport System is comprised of a sterile peel pouch containing a polyester flock swab applicator for collecting specimen and a polypropylene vial

containing 1 ml of modified Amies liquid transport medium. The polyester flock swab applicators are provided in two different tip sizes to accommodate various specimen types.

Amies liquid medium is a nonnutritive balanced salt solution containing inorganic phosphates to provide buffering capability, sodium chloride, potassium chloride, calcium chloride and magnesium chloride to provide essential ions that help maintain osmotic balance. Sodium thioglycollate provides a reduced environment. It is recommended for maintaining the viability of aerobic, anaerobic and fastidious bacteria during the transport to the laboratory.

5.6 Intended Use

Puritan Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

5.6.1 Indication(s) For Use

Puritan Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

5.7 Substantial Equivalence statement

Puritan Liquid Amies Collection and Transport Systems is similar in design, manufacturing and intended usage to the predicate device. Both Puritan and predicate devices are single-use devices intended for collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria.

Puritan Versus Competitor Similarities		
Item	**Test Device**	**Predicate**
Intended Use	Collection and transport of clinical specimens from the patient to the laboratory for bacterial examination and culture	Same
Single-use Devise	Yes	Yes
Medium Formulation	Sodium chloride Disodium phosphate Sodium thioglycollate Monopotassium phosphate Potassium chloride Calcium chloride Magnesium Chloride	Same
pH	7.3 ± 0.2	Same
Storage Temperature	2-25□C (refrigerated and room temperature)	Same
Container	Plastic; conical bottom	Same
Product Configuration	Medium in tubes & Cap System including Medium and swab in peel pouch option.	Same
Swab Shaft	Plastic	Same

Puritan Versus Competitor Differences		
Item	**Device**	**Predicate**
Swab Tip	HydraFlock Swab (Polyester)	Nylon Flock swab
Shelf Life	18 months	15 months

5.8 Recovery Testing

To determine the ability of the Puritan Amies liquid medium to maintain viability of different strains of aerobes, anaerobes and fastidious bacteria, known inocula of ATCC type culture and clinically significant microorganisms were inoculated into the Puritan liquid Amies transport medium and compared to the predicate device following Clinical and Laboratory Standards Institute(CLSI), M40-A guidelines. The Puritan Liquid Amies system showed recovery of bacteria within the acceptance criteria like the predicate device.

5.9 Stability Testing

Stability tests were performed on Puritan Amies liquid products to verify the ability of the aged products to maintain microbial recovery up to the expiry date.

5.10 pH Stability

The pH of the test device was measured at predetermined time intervals up to 18 month after manufacturing date. The test was performed using calibrated pH meter with random samples from three different lots of Puritan Liquid Amies Collection and Transport System. All samples tested were found to maintain pH within the specified range.

5.11 Cytotoxicity

Cytotoxicity test was conducted to evaluate glue, shaft and the polyester (flock) swabs for potential cytotoxicity effect following ISO Elution Method-1X MEM Extract. No evidence of cytotoxicity was detected.

5.12 Sterilization

Puritan Liquid Amies Transport Systems are sterilized by gamma irradiation and validated following ANSI/AAMI/ISO 11137:2006, Sterilization of health care products radiation guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Puritan Medical Products LLC.
c/o Mehdi Karamchi B. Sc. RM (ccm)
Vice President of Scientific Affairs
31 School Street, PO Box 149
Guilford, ME 04443-0149

JUN - 8 2012

Re: K120846
Trade/Device Name: Puritan® Liquid Amies Collection and Transport System
Regulation Number: 21 CFR 866.2900
Regulation Name: Microbiological specimen collection and transport device
Regulatory Class: Class I
Product Code: LIO, JTW, JTX
Dated: March 20, 2012
Received: March 20, 2012

Dear Mr. Karamchi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

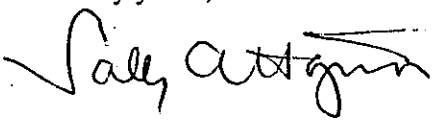
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K120846

Device Name: Puritan® Liquid Amies Collection and Transport System

Indications for Use:

Puritan® Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobic, anaerobic and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Tamara Feldblyum

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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